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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/766,362	01/19/2001	Solomon S. Steiner	PDC 119	8907

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EXAMINER

SHEIKH, HUMERA N

ART UNIT PAPER NUMBER

1615

DATE MAILED: 12/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Advisory Action</b>	<b>Application No.</b> 09/766,362	<b>Applicant(s)</b> STEINER ET AL.	
	<b>Examiner</b> Humera N. Sheikh	<b>Art Unit</b> 1615	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 13 October 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY [check either a) or b)]**

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b) ☐ they raise the issue of new matter (see Note below);
  - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☒ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

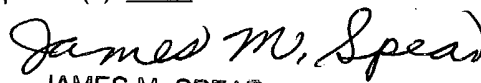
Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 1-5, 7-12, 14-18, 20 and 21.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☐ The drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_

  
 JAMES M. SPEAR  
 PRIMARY EXAMINER  
 AU 1615

Continuation of 2. NOTE: Applicant's current claim amendment reciting a particle size of "greater than 10 microns and up to 20 microns" is a new claim limitation not previously presented earlier during prosecution. The previous search was based on particles having an average particle size of 'between 10 and 20 microns.' Thus, the claims as now presented would require further consideration and/or search by the Examiner. Also, a review of the instant specification indicates, that while the Examples yield particle sizes averaging between 10-20 microns, the support for amendment citations by Applicant (pg. 2, lines 5, 10 & 21) demonstrates specification language reciting "between 10 and 20 microns" or "between approximately 10 and 20 microns", but does not recite "greater than 10 microns and up to 20 microns" as now claimed by Applicant. Applicant is kindly requested to specifically point out where in the instant specification the recitation of particles having "greater than 10 microns and up to 20 microns" can be found.

Continuation of 5. does NOT place the application in condition for allowance because: The art teaches nasally-administered particle formulations, having particles sizes of 'between 0.1 and 10 microns' (Steiner) and 'between 10 and 100 microns' (Illum). Applicant's have not demonstrated any criticality in the currently claimed particle sizes. The art recognizes effectively administering drug particles to systemic regions using the particle sizes taught in the art. Applicant's arguments that the instant invention does not require the 'formation of a gel or the addition of absorption enhancers' is not persuasive since the instant "comprising" claim language permits the inclusion of additional components besides from those instantly recited.

*James M. Spear*  
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